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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/591,540 | 09/01/2006 | Claus Frohberg | 65084.000023 | 2168 |

21967 7590 03/22/2010
HUNTON & WILLIAMS LLP
INTELLECTUAL PROPERTY DEPARTMENT
1900 K STREET, N.W.
SUITE 1200
WASHINGTON, DC 20006-1109

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| EXAMINER |
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PAGE, BRENT T

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| ART UNIT | PAPER NUMBER |
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1638

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| MAIL DATE | DELIVERY MODE |
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03/22/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/591,540 | Applicant(s) FROHBERG ET AL. | |
| | Examiner BRENT PAGE | Art Unit 1638 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23, 25-27 and 29-37 is/are pending in the application.
- 4a) Of the above claim(s) 20-23 and 25-27 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2, 3 and 30-37 is/are allowed.
- 6) ☒ Claim(s) 1, 4-19 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The Reply filed by Applicants on 11/24/2009 is hereby acknowledged. The addition of New claims 30-37 are hereby acknowledged. Claims 20-23 and 25-27 remain withdrawn as being drawn to nonelected subject matter. Claims 1-23, 25-27 and 30-37 are pending. Claims 1-19, and 29-37 are examined herein on the merits. A closer review of the rules regarding written description has necessitated a new ground of rejection below, and accordingly this action is NON-FINAL.

Specification

Applicant's arguments, see page 14 of the response, filed 11/24/2009, with respect to embedded hyperlinks have been fully considered and are persuasive when taken together with the amendments to the specification. The objection to the Specification for containing embedded hyperlinks has been withdrawn.

Claim Rejections - 35 USC § 112-2nd paragraph

Applicant's arguments, see page 15 of the response, filed 11/24/2009, with respect to indefiniteness have been fully considered and are persuasive when taken together with the claim amendments. The rejection of claims 12-15 under 35 USC 112 2nd paragraph as being indefinite has been withdrawn.

Claim Rejections - 35 USC § 112-1st paragraph

Applicant's arguments, see pages 15-16, filed 11/24/2009, with respect to to written description and enablement regarding producing a plant with reduced OK1 protein activity by a genetic modification that increases the activity have been fully considered and are persuasive when taken together with the claim amendments. The rejection of claims 12-15 under 35 USC 112 1st paragraph for lacking written description and lacking enablement on the ground of the typographical error has been withdrawn. However, a closer inspection of written description rules and the breadth of the claims has necessitated the new ground of rejection as set forth below for claims 1, 4-19, and 29.

Claims 1, 4-19, and 29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a genetically modified plant cell with a reduced activity of at least one OK1 protein comprising at least one foreign nucleic acid wherein the foreign nucleic acid is an antisense RNA, a DNA molecule acting by co-suppression, a double stranded RNA molecule, a plant cell synthesizing modified starch comprising said reduced activity, a plant comprising said plant cell, a method of manufacturing a genetically modified plant, a recombinant

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nucleic acid molecule comprising a promoter and at least one foreign nucleic acid wherein the foreign nucleic acid is an antisense RNA, a DNA molecule acting by co-suppression, a double stranded RNA molecule, and a composition comprising said recombinant nucleic acid and a host cell with a vector comprising said foreign nucleic acid.

In contrast, the specification only describes cells, plants and vectors that comprise a foreign nucleic acid wherein the foreign nucleic acid is a nucleic acid molecule that encodes an OK1 protein. The specification does not describe any other foreign nucleic acids when introduced into a cell would reduce the expression of the OK1 protein. In addition to transcription factors, it is known that the OK1 protein requires the phosphorylation of starch by the R1 protein in order to phosphorylate starch, meaning that at least one more if not multiple foreign nucleic acid molecules might exist that would reduce the expression of the OK1 protein. However, the specification does not describe any other genes, nor describe what structures would be sufficient in reducing the activity of the OK1 protein. There are literally thousands of genes that when suppressed or when over-expressed might reduce the expression of the OK1 protein. While there are several working examples in the specification of molecules that reduce the expression of the OK1 protein, all of said examples encode at least a portion of the OK1 protein, which as a single example is not representative of the genus of genes that may be capable of reducing the expression of the OK1 protein.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an

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invention “requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials.” *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that “naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.” *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to “visualize or recognize the identity of the members of the genus.” *Id.*

Finally, the court held:

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Id.*

See also MPEP section 2163, page 174 of chapter 2100 of the August 2005 version, column 1, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

See also *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

Given the claim breadth and lack of description as discussed above, the specification fails to provide an adequate written description of the genus of sequences as broadly claimed. Given the lack of written description of the claimed genus of sequences, any method of using them, such as transforming plant cells and plants therewith, and the resultant products including the claimed transformed plant cells and plants containing the genus of sequences, would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing. See the Written Description Requirement guidelines published in *Federal Register*/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111.

Claim Rejections - 35 USC § 102

Applicant's arguments, see pages 16-17, filed 11/24/2009, with respect to anticipation by Frohberg in light of Ritte et al have been fully considered and are persuasive when taken together with the claim amendments requiring a reduction in the expression of the OK1 protein. The rejection of claims 1-2, 4-19 and 29 under 35 USC 102(b) as being anticipated by Frohberg has been withdrawn.

Applicant's arguments, see pages 18-19, filed 11/24/2009, with respect to anticipation by Kikuchi et al have been fully considered and are persuasive when taken together with the claim amendments and the agreement during the

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interview of 11/12/2009 with Applicants and Anne Marie Grunberg that the amount of sequences, the lack of the reduction to practice the silence in regard to the activity of SEQ ID NO:22133. The rejection of claims 1-7, 9-11, 16-19 and 29 under 35 USC 102(e) as being anticipated by Kikuchi has been withdrawn.

Double Patenting

Applicant's claim amendments, see claims, filed 11/24/2009, have rendered the Double Patenting rejection of record moot. The co-pending applications do not claim the reduction of OK1 activity or expression. The provisional rejection of claim 12 under nonstatutory obvious-type double patenting is hereby withdrawn.

Claims 2-3 and 30-37 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRENT PAGE whose telephone number is (571)272-5914. The examiner can normally be reached on Monday-Friday 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Examiner, Art Unit 1638